

REMARKS

Claims 5-11 have been canceled. New claims 13-17 have been added. Claim 13, which is directed to a solid or semi-solid pharmaceutical composition, now states that the matrix phase contains an active ingredient as disclosed on page 3, lines 16-17 of the specification. Claim 13 also adds hydroxy alkyl cellulose and cellulose esters to the list of components forming the matrix (page 3, lines 36-37 of the specification). Claim 14 is the same as canceled claim 9. Claim 15 is the same as canceled claim 10.

The examiner rejected claims 5-11 as being anticipated by Klimesch et al. The rejection is made because, according to the examiner, melt extrusion is disclosed (column 2 lines 45-47), PVP is specified (column 2 line 51), flavorings are disclosed (column 4, line 9), theophyllines are specified (column 4 line 39), and as to the claimed particulate the anticipatory composition must possess such because theophylline melts at 270-274°C whereas Klimesch disclose extrusion temperatures of 50-180°C (column 2 lines 64-65).

Lack of novelty can only be established by a single prior art reference which discloses each and every element of the claimed invention. *RCA Corp. v. Applied Digital Data Systems, Inc.*, 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). Above claim 13 specifies that the matrix contains an active ingredient in the form of a solid solution. Klimesch et al. does not teach this element. Therefore, there should now be no anticipation of the claims.

Claims 5-10 are rejected under 35 USC § 112, first paragraph, because the

specification, while being enabling for a drug in the second phase or in both phases, does not reasonably provide enablement for a drug only in the matrix. In view of the new set of claims which specify that the matrix contains an active ingredient in the form of a solid solution, applicants believe this rejection no longer should stand.

✓ Claims 5-11 were rejected under obviousness type double patenting as being unpatentable over claims 3 and 13 of US 6,001,391. Applicants submit a terminal disclaimer on separate paper to overcome this rejection.

Attached is a check in the amount of \$110.00 to cover the one month extension fee.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

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